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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/087,222 | 03/01/2002 | Michael Kloss | 279.287US1 | 6921 |

21186 7590 01/26/2005

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MINNEAPOLIS, MN 55402

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| EXAMINER |
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MULLEN, KRISTEN DROESCH

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| ART UNIT | PAPER NUMBER |
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3762

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/087,222 | | KLOSS ET AL. | |
| | Examiner | | Art Unit | |
| | Kristen Mullen | | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/29/04 (response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/14/03, 10/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: lack of antecedent basis for the average of minute ventilation values.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims, 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining minute ventilation values are increasing, does not reasonably provide enablement for determining that the average minute ventilation values are increasing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use and make the invention commensurate in scope with these claims. The specification provides for determining when minute ventilation values are increasing (A8) and determining the mean amplitude of the oscillatory component of the minute ventilation (A2) in order to compare the mean amplitude of the oscillatory component to a threshold. See Page 13, line 15-Page 14, line 22 of the Specification and Fig. 4. Claim 1 contains the limitation “an average of those minute ventilation values are increasing” in lines 4-5. Claim 10 contains the limitation “the average minute ventilation continues to increase”.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 10 recites the limitation "the average of the minute ventilation values continue to increase" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim.

Allowable Subject Matter

7. Claims 1-20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph and 2nd paragraph, set forth in this Office action. Claims 1, and 10 require deletion of references to "average" minute ventilation values to overcome the 112 35 U.S.C. 112, 1st paragraph rejection. Claim 10 requires proper antecedent basis for "minute ventilation values continue to increase".

The prior art of record fails to teach or suggest a rate adaptive pacer comprising a controller configured to or a method comprising measuring minute ventilation values and determining that those minute ventilation values are increasing, determining an amplitude of an oscillatory component in the measured minute ventilation values to be above a specified threshold value and, if the amplitude of the oscillatory component falls below the specified threshold value as the minute ventilation continues to increase, and setting the breakpoint of the rate response curve equal to the presently measured minute ventilation value.

Kay et al. (6,411,850) shows determining a breakpoint in a rate response curve by measuring respiratory rate and minute ventilation during submaximal exercise and developing a

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regression analysis. Sun et al. (6,490,485) shows determining a breakpoint in a rate response curve by measuring the number of times and the extent the MV signal input exceeds threshold values.

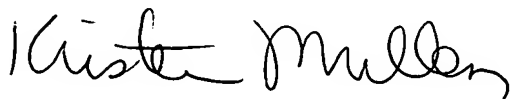
Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sun et al. (6,823,214) and Sun et al. (6,839,593) each show determining the rate response function including the breakpoint based on stored maximum exertion levels (MV levels).

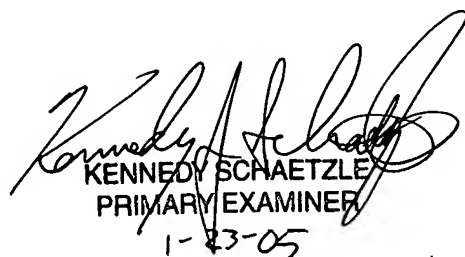
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



kdm


KENNEDY SCHAETZLE
PRIMARY EXAMINER
1-23-05